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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,823	06/07/2001	Rolf Ehrhardt	05882.0003.P	2366

27194 7590 04/22/2003

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EXAMINER	
DECLOUX, AMY M	

ART UNIT	PAPER NUMBER
1644	12

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,823	EHRHARDT ET AL.	
	Examiner	Art Unit	
	Amy M. DeCloux	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-27 and 33-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-27 and 33-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 June 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☑ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5,7* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II, claims 25-27 and 33-42 in Paper No. 11, filed 2-6-03, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Objections

2. Claim 33 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Information Disclosure Statement

The office does not have the references listed on the 1449 form filed by Applicant 6-7-01 (Paper No.3), and therefore, said IDS has not been considered. Applicant is kindly requested to send the office another copy of the references.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 27 and 38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that antibodies HuZAF and 2F2, 16F2, 16G2, 20E11 are required to practice the claimed invention. As a required element, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification.

In addition, the identifying information set forth in *37 C.F.R. 1.809 (d)* should be added to the specification. *See 37 C.F.R. 1.803-1.809* for additional explanation of these requirements. Amendment of the specification to disclose the date of deposit and the complete name and address of the depository is required.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that **all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent**, would satisfy the deposit requirements. *See 37 C.F.R. 1.808.*

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 25-26, 33-37 and 39-42 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 98/16248 (IDS), as evidenced by US-PAT-NO: 5,440,021.

'248 teaches the oral administration of a monoclonal antibody that binds IL-12 for the treatment of psoriasis (see entire patent including the Abstract, page 5, line 15, page 7, lines 15-27, Claims 8 and 18). Said patent also teaches that said monoclonal antibody can be humanized or can be fragments thereof, wherein said fragments maintain IL-12 binding activity, (see entire patent, including lines 1-10 of page 7). Said patent also teaches that the dosage can be between .0001 and 100 mg/kg/body weight/day, (see entire patent, including lines 10-30 of page 8, and lines 14-21 of page 9). Claim 42 is included because the reference teaches on page 11 that the dosage can be adjusted once it is established that the disease is significantly improved, which would inherent to the claimed limitation that said treatment reduces PASI by at least 50%. Claim 36 is included because Claim 36 is included because the limitation of a monoclonal antibody with a binding affinity of at least 10^8 M is typical of blocking antibodies as evidenced by US-PAT-NO: 5440021 which teaches that monoclonal antibodies against IL-8 with an affinity approximately similar to the instantly recited affinity were able to inhibit binding 80% of IL-8 binding. Therefore, the referenced teachings anticipate the claimed invention.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 25-26, 33-37 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,338,848, in view of Menssen et al. (J. Immunology, 1995, 155:4078-4083), and in view of US-PAT-NO: 5,440,021.

'848 teaches a method of treating autoimmune diseases comprising the administration of an IL-12 antagonist, wherein said autoimmune disease is promoted by an increase in levels of IFN gamma, (see entire patent, especially the Abstract). Said patent also teaches that said monoclonal antibody can be humanized or can be fragments thereof, wherein said fragments interfere with IL-12 binding activity, (see entire patent, including lines 1-15 column 4). Said patent also teaches that the dosage can be between .0001 and 100 mg/kg/body weight/day, (see entire patent, including lines 40-50 of column 2 and lines 64-67 of column 6), and that said dosage can be administered IV in a pharmaceutical solution (se entire patent including column 7, lines 1-10). '848 also teaches that the administration would continue until a meaningful patient benefit is observed by the treatment provider (see entire patent, including column 7, lines 10-44).

'848 does not teach that psoriasis is an autoimmune disease that is promoted by an increase in levels of IFN gamma.

Menssen et al teach that psoriasis exacerbations can be triggered by systemic administration of IFN gamma and that psoriasis is driven by autoantigens, (see entire article, including column 1 of pages 4078 and 4083).

'021 teaches as above.

Therefore, it would have been obvious to one of skill who wanted to treat psoriasis to have administered a monoclonal antibody that binds IL-12 to a patient with psoriasis in according to the method of '848 described above because '848 teaches that that administering an IL-12 antagonist is effective in treating an autoimmune disease that is promoted by an increase in IFN gamma, and because Menssen et al teach that psoriasis exacerbations can be triggered by systemic administration of IFN gamma. Further it would have been obvious to use a monoclonal antibody with an affinity of at least 10^8 M because '021 teaches that said affinity is typical of blocking antibodies. Further it would have been obvious to administer a dosage which would reduces PASI by at least 50% because '848 also teaches that the administration would continue until a meaningful patient benefit is observed by the treatment provider .

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872-9306 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.
Patent Examiner,
April 18, 2003

Patrick J. Nolan, Ph.D.
Primary Patent Examiner
Group 1640